K053137

JUN 14 2006

Section 8 510(k) Summary

510(k) Summary

Prepared October 12, 2005

Submitted by:	MD Scientific LLC
Submitter's Address:	1214 Wareham Court Charlotte, NC 28207
Contact Person:	Shade M. Mecum 704-335-1300
Product Trade Name:	EndoTool™ Glucose Management System
Common Name:	Drug Dose Calculator
Classification:	Class II (per 21 CFR 868.1890
Predicate Device:	TRxF Intelligent Dosing System™ (K011571)
Description of Device:	EndoTool™ Drug Dose Calculator is software that resides on a Microsoft/Intel platforms to calculate (see Section 9.2, page 20) the drug dose of insulin to control blood glucose levels for critically ill patients on continuous feeding (IV, TBN, or tube feeding).
Intended Use:	This software is to be used by trained nurses with supervision from licensed medical providers with appropriate hospital privileges or directly by licensed medical providers with appropriate hospital privileges in operating rooms, recovery rooms, and intensive care units to calculate the dose of insulin expected to maintain the blood glucose level in a range selected by the attending physician.

Comparison with Predicate Devices:
The Submission device and the predicate devices have the same intended use to calculate any individual's optimum next dose. Both devices are to be used by trained clinicians. The main difference is the patient using this submission device is limited to patients receiving continuous feeding.

The absence of intermittent feeding reduces the complexity of a variety of nutritional sources on blood glucose levels.

Safety and Effectiveness Concerns:
This system is compliant to applicable standards ANSI/IEEE 1012 (Standards for Software Verification and Validation) and ANSI/IEEE 830 (Guide to Software Requirement Specifications)

Conclusion:
This EndoTool™ Drug Dose Calculator system has the same intended use and characteristics and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 2006

MD Scientific LLC
% Mr. Shade M. Mecum
President
1214 Wareham Court
Charlotte, North Carolina 28207

Re: K053137
Trade/Device Name: EndoTool™ Drug Dose Calculator
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulation Class: II
Product Code: NDC
Dated: May 22, 2006
Received: June 8, 2006

Dear Mr. Mecum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): (Unknown) K053137

Device Name: EndoTool™ Drug Dose Calculator

Indications For Use:

The EndoTool™ Drug Dose Calculator is a software support system designed for use by trained healthcare professionals to calculate any individual patient's optimal next dose for insulin administered intravenously to control blood glucose level for critically ill patients without inducing hypoglycemia (low blood glucose levels). EndoTool™ is for use with patients who are receiving a relative constant nutritional intake via intravenous fluids with dextrose, total parental nutrition or continuous gastro-intestinal feedings by any route of delivery.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K053137

Concurrence of CDRH, Office of Device Evaluation (ODE)